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10/039,291	01/03/2002	Colette Cozean	COZEAN.001A	8339

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EXAMINER

KRASS, FREDERICK F

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/039,291

Applicant(s)

COZEAN ET AL.

Examiner

Frederick F. Krass

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) 1-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Art Unit: 1614

Prior Rejections

Unless specifically repeated hereinafter, all previous rejections are withdrawn.

Duplicate Claim Warning

Claim 50 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 51.

When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Written Description Rejection: New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 37-43 and 45-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a "new matter" rejection.

Claim 37, second line, no support is seen in the specification as originally filed for reciting a "viscous" fluoride mixture generally. The specification discloses only two specific physical forms of fluoride mixtures, namely gels and pastes as recited by instant claim 44 (which is not rejected herein).

Art Unit: 1614

Scope of Enablement Rejection

Claims 37-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for systems that “minimize” structural damage to teeth, does not reasonably provide enablement for systems that “prevent” structural damage to teeth (as recited at the penultimate line of claim 37). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdAplis 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence or absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art, and
- 8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth hereinbelow.

1. The nature of the invention, state of the prior art, relative skill of those in the art, and the predictability of the art

The claimed invention relates to systems for treating teeth. The relative skill of those in the art is that of a D.D.S. While this level of skill is relatively high, it is outweighed by the unpredictability of preparing a system to “prevent”, i.e. completely eliminate, structural damage to the teeth. Even the layman, e.g. the ordinary consumer of oral care products, will readily

Art Unit: 1614

recognize that such structural damage cannot be "eliminated"; the best that can be hoped for is minimization of harm. No definitive "prevention" of tooth damage is realistically possible; there will always be minimal damage (especially on the microscopic level), no matter how careful the administration.

2. The breadth of the claims

The claims are very broad insofar as they recite systems which "prevent" structural damage to teeth.

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification and working examples provide no direction or guidance for preventing structural damage to teeth. They disclose only what is already known, i.e. minimizing damage through cautious application.

4. The quantity of experimentation necessary

The instant specification provides no examples of or guidance for preventing, i.e. completely eliminating, structural damage to teeth, so one would have to resort to extensive and undue experimentation to achieve same - if it is in fact possible at all. (Perhaps "prevention" could in theory be achieved under certainly strictly controlled extreme conditions, but no such conditions are disclosed).

5. Suggested Alternative Language

This rejection can be overcome by replacing the word "prevent" at the penultimate line of claim 37 with a less absolute term, e.g. --- minimize ---

Art Unit: 1614

Indefiniteness Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

i) The term "viscous" in claim 37 is a relative term which renders the claim indefinite, as well claims 38-43 and 45-54 which depend therefrom. The term "viscous" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The specification appears in fact to disclose only those fluoride mixtures which are sufficiently viscous to be self-supporting, i.e. gels and pastes. It is not clear from the teachings of the specification as originally filed whether a non self-supporting mixture, e.g. a liquid, would be within the scope of the newly recited term "viscous".

ii) The term "substantially" at the penultimate line of claim 37 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Moreover, since "prevent" is an absolute term (see the "Enablement Rejection" above), the function of "substantially" in modifying same is not clear.

Obviousness Rejection (New)

Claims 37-40 and 44-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boutoussov et al (USP 6,439,888) in view of Alvarez Hernandez (USP 6,419,905).

The primary reference discloses a handheld device (a "home treatment system") comprising an LED light source which produces wavelengths in the range of from 400 to 750nm (i.e. blue light: see col. 6, lines 63 and 64), at an energy density of no greater than 14 Joules (col. 9, lines 45-48). This is the same light source claimed instantly, and thus it would inherently possess all the adaptive characteristics recited, including minimizing tooth damage, facilitating subsurface penetration of fluoride, and heating the teeth to a temperature of less than 250 degrees Celsius. A "fluoride maintenance source" as required by instant claim 45 is also disclosed (col. 8, lines 65-67; col. 9, lines 55-58).

The primary reference differs from the instant claims insofar as it does not disclose a treatment system comprising a viscous fluoride mixture and an LED light source. (The fluoride gel (toothpaste) disclosed by the prior art is used in a later separate treatment and thus is not cooperatively associated with the LED so as to form a "system"). It does, however, disclose methods for tooth bleaching (col. 2, lines 6-17), and teaches that a variety of known bleaching compositions are suitable for use therewith (col. 9, lines 13-26).

The secondary reference discloses tooth bleaching gels which contain 0.15 to 3 percent by weight of a fluoride salt, e.g. sodium fluoride. See col. 1, line 6, col. 3, lines 49-59, col. 4, lines 10 et seq., and col. 5, line 25. Inclusion of the fluoride salt is taught to be desirable because it minimizes post-bleaching sensitivity (see col. 6, lines 23-25). The secondary reference differs from the instant claims insofar as it is silent regarding using a LED light source.

It would have been obvious to have used a bleaching gel containing 0.15 to 3 percent by weight fluoride to whiten teeth with an LED light source as taught by the primary reference, motivated by the desire to minimize post-bleaching sensitivity as taught by the secondary reference.

Art Unit: 1614

Allowable Subject Matter

Claims 41-43 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, first and second paragraphs, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The prior art of record does not fairly suggest, teach or disclose using a fluoride mixture having a fluoride concentration in the range of about 0.002 ppm fluoride to about 45 ppm fluoride. Note, for example, that USP 6,419,905 uses amounts orders of magnitude greater (0.15 to 3 percent by weight: see col. 1, line 6 and col. 5, line 25)).

Furthermore, Applicant has demonstrated that when such extremely low amounts of fluoride are used in the instantly claimed systems, unexpected synergistic results are obtained. (See, for example, the first two paragraphs of page 14 of the instant specification). This could in no way have been predicted from the prior art of record.

Action is Final, Necessitated by Applicant's Amendment

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 1614

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is as follows:

Monday: 10:30AM- 7PM;
Tuesday: 10:30AM - 7PM;
Wednesday: off;
Thursday: 10:30AM- 7PM; and
Friday: 10:30AM-7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614

